

INVENTOR: McBride et al
TITLE: MEDICAL TESTING AND METHOD

attorney docket: CARDIOBEAT-1

The claims have been amended to point out the applicability to impedance cardiography which is not shown, taught or even remotely suggested in the references. The amendments are made solely to advance prosecution of this application and are specifically not intended as any admission or concession that the rejections set forth by the Examiner are being conceded to. Applicant expressly reserves the right to reinstate the broader claims that were presented in the prior amendments and expressly reiterates that the references taken either singly or in combination do not show, teach or suggest the novel inventions that were presented in the claims prior to this amendment.

Claim 1 recites:

providing non-invasive test sensors for a subject; coupling said test sensor to said subject; coupling said test sensors to impedance measuring apparatus having access to the Internet; operating said apparatus to automatically obtain test measurement impedance data from said test sensors; uploading said test measurement impedance data via the Internet to a location remote from said subject; providing a server at said remote location; processing said test measurement impedance data at said central server to produce processed impedance cardiography data; downloading said processed impedance cardiography data from said server to said apparatus, and displaying said processed impedance cardiography data at said apparatus.

The Examiner points to Brown '263 as showing a test sensor and coupling the test sensor to a subject. In support of this contention, the examiner points to blood glucose monitor 16, a peak flow meter 20 and to an additional monitor 22. However, none of a glucose monitor, peak flow meter or additional monitor are "test sensors".

Merriam-Webster's on-line dictionary defines "sensor" as:

a device that responds to a physical stimulus (as heat, light, sound, pressure, magnetism, or a particular motion) and transmits a resulting impulse (as for measurement or operating a control)

and defines "monitor" as:

a device for observing a biological condition or function <a heart *monitor*>

A sensor is a device that senses something. A "monitor" is something that monitors or observes something. A sensor is not a monitor. A monitor is not a sensor.

In the last amendment filed by Applicant it was stated that:

The Examiner now points to col. 15, lines 33-34 to support his contention that Brown teaches sensors. However, *the passage pointed to by the Examiner does not, properly read, support the Examiner's contention.* The passage relied on recites in totality:

"Formatting a standardized report 56 (i.e., analyzing and processing data supplied by a blood glucose monitor 16 or other monitor or sensor) can be

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effected either by data management unit 10 or within the clearinghouse facility 54."

In the context of the entirety of the disclosure of the teachings of Brown, the "sensor" is not a test sensor. In fact the passage pointed to by the Examiner supports Applicant's contention that the "sensor" of Brown is not a test sensor. It is apparent that the Examiner is looking only at words and not reading the reference for how it utilizes the words to determine the context.

The Examiner has not responded to this statement and it is therefore considered that the Examiner's silence on that position is either agreement with the statement or is acquiescence to the statement. Accordingly, Applicant is entitled to rely upon the Examiner's silence especially in view of the MPEP admonition against "piccmeal" prosecution.

Still further, claim 1 recites that the sensors are "non-invasive test sensors."

Even if Brown '263 or Brown '163 is erroneously considered to describe or infer the use of a sensor, the monitoring devices are not "non-invasive." Glucose monitoring devices require the use of bodily fluids and are inherently invasive in that at least a drop of blood is utilized. Similarly, flow monitors must penetrate the body to measure any flow.

Accordingly, neither Brown reference shows, teaches or suggests a "non-invasive test sensor."

On the foregoing bases, the Brown references do not show, teach or suggest the use of sensors as called for in claim 1 nor do they show, teach or suggest the use of non-invasive sensors.

The Reining reference is directed to a stand alone impedance measuring system. There is no suggestion in Reining that the system of Reining has applicability to a system such as taught by Brown '263. Reining does not show, teach or suggest transferring sensor data remotely to a server as stated by the Examiner. Reining is absolutely silent about remote access. To the contrary, Reining shows and teaches use of a wireless arrangement in which an infrared link is utilized. (col 4, lines 44-52). The use of infrared is a clear indication that the apparatus is not and can not be "uploading said test measurement impedance data via the Internet to a location remote from said subject" as called for in claim 1. Accordingly, although the Examiner cites Reining as teaching measuring impedance, he can not only pick portions of the teachings and ignore other teachings. The Examiner must consider the entirety of the teachings of Reining.

It is further pointed out that Brown '163 at col. 6, lines 10-23, incorporates the teachings of Brown '263. It is clear from a reading of Brown '163 that it is not contemplated to use the Internet for the uploading of test measurement data from sensors to a server at a remote location for processing. Since Brown '163 already has incorporated the teachings of Brown '263, it is respectfully submitted that the Examiner's construction that:

"It would have been obvious to one of ordinary skill in the art, at the time of the invention, to modify Brown (US 5,307,263), so that data is communicated via Internet as

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taught by Brown et al (US 5,879,163), so as to be able to communicate data through a common medium for cost efficiency.”
is contrary to the plain teachings of the ‘163 patent.

Still further, Brown is silent on communicating data via the Internet “so as to be able to communicate data through a common medium for cost efficiency.”

If the Examiner does not withdraw these positions, it is respectfully requested that he point with specificity where support for such all encompassing statements are found in any of the references.

Still further, the Examiner characterizes Brown ‘263 as:

“providing a server at a remote location (fig. 2, part 54), processing the measurement data at the central server to produce processed data (col. 12, lines 16-26), downloading the processed data from the server to the apparatus (col. 12, lines 26-28), and displaying the information (figs 5-10 and col. 19, lines 52-61).”

However, it is respectfully requested that the Examiner has misread or does not appreciate the teachings of Brown ‘263.

It is clear from a reading of Brown ‘263 in its entirety, that the blood glucose monitor produces processed data and that the “server” or clearinghouse 54 does not process data from test sensors to produce processed data for downloading back to the local apparatus for display. Rather, it is clear that the clearinghouse 54 serves to provide data conversion to different types of equipment and to provide for a central storage of data. The processing of sensed data is at all times in Brown ‘263 performed at the patient apparatus.

Accordingly, the references taken singly or in combination do not show, teach or make obvious the invention of claim 1.

Furthermore, since all the claims in the application depend from claim 1 and add further limitations, all the claims in the application are likewise not shown, taught or made obvious by the references taken singly or in combination.

It is also pointed out that applicant has claimed specific structures and not generalized functionalities. Accordingly, the Examiner’s statement of generalizations at the bottom of page 2 is not appropriate. The Examiner is reminded that he must take each reference for what it fairly teaches within its four corners.

The Examiner’s attention is again drawn, in particular, to MPEP 706.02(j) and MPEP 2143 and the **three basic criteria that must be set out to establish a prima facie case of obviousness.**

The first criteria is that “there must be some suggestion of motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.”

“Second, there must be a reasonable expectation of success.”

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"Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicants disclosure." MPEP 2143 quoting *In re Vaeck*

MPEP 706.02(j) quotes *Ex Parte Clapp*: "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention, or the Examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to be obvious in light of the teachings of the references."

MPEP 2143.01 clearly points out that the "level of skill in the art cannot be relied upon to provide the suggestion to combine references" *Al-Site Corp. v. VSI Int'l Inc.*

MPEP 2143.01 further provides the clear guidance that: "A statement that modifications of the prior art to meet the claimed invention would have been 'well within the ordinary skill of the art at the time the claimed invention was made' because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references." citing *Ex parte Levengood*

MPEP 2143.01 further clearly provides the guidance that the proposed modification of the prior art cannot change the principle of operation of the prior art reference.

The Examiner's attention is also directed to MPEP 2144.03 which clearly sets forth the standards, in accordance with *In re Zurko* and the other cases cited therein, for reliance on "well known" prior art. The Examiner's attention in particular is directed to 2144.03 C wherein "If applicant challenges a factual assertion as not properly officially noticed or not properly based upon common knowledge, the Examiner must support the finding with adequate evidence."

Claims 4-20 all depend from claim 1 and for the same reason that Brown '263 and Brown '163 in combination with Reining do not show, teach or make obvious claim 1, claims 4-20 are not shown, taught or made obvious by Brown '263 and Brown '163 and Reining.

The Examiner in rejecting claim 10 which recites, inter alia: "automatically storing processed data for test measurement data obtained at different times for said subject as said additional processed data" states that Brown '263 "teaches data being stored at different times." However, the passage relied on by the Examiner is specific to blood glucose measurements only.

Accordingly, for this additional reason, claim 10 is not shown, taught or made obvious by the references taken singly or in combination.

Claims 11-17 depend from claim 1, and for the reasons set forth above, claims 11-17 are not shown, taught or made obvious by Brown '263 in combination with additional references.

The Examiner has stated that the Applicants arguments set forth in the prior filing have been considered, but "are moot in view of the new ground(s) of rejection."

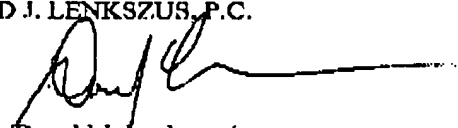
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is further requested that the claims be allowed and that this application be passed to issue. An early notice of allowance would be appreciated.

Respectfully submitted,
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However, the Examiner follows that statement with arguments that are not applicable to the claims since the Examiner has set forth new bases for rejection.

However, because the Examiner has presented arguments, Applicant will respond to those arguments.

The Examiner points to Figure 1 and state that "the relationships among parts 10, 52, and 54 of figure 1 which clearly shows a network."

No network is shown in Figure 1. All that is shown is a data management unit 10, a modem 52, and a clearing house 54. It is respectfully requested that none of those three elements shows or inherently suggests a network. Data management unit 10 provides for local connecting of the various monitor units. A modem is strictly a signal conversion device. There is no indication that the clearing house 54 is inherently connected to a network. Still further, claim 1 does not recite a network, but rather claim 1 recites the Internet. Even if a network was shown, it is not the Internet, and there is no inherency that any network is the equivalent of the Internet.

In addition, once again it is pointed out that the Examiner has misread Halpern. The cited passage is absolutely silent on use of any analysis program. The passage cited states: "When the portable computer 22 requests historical data from the modules 16, the data is retrieved from the memory 84." **Halpern is silent on providing analysis of historical data and using an analysis program as called for in claims 11-17.**

In the prior office action, the Examiner improperly attempted to fill the voids in the teachings of the references at page 5 by stating without any substantiation that: "because analyzing data is well known in the art, it would have been obvious to one of ordinary skill in the art (sic), at the time of the invention to modify Brown...."

Now the Examiner merely varies that improper argument by stating:

"It is inherent that a software program is needed in order to have the ability to analyze data stored in memory modules."

Where is the analysis program as called for in the claims? The Examiner makes an unwarranted leap in his analysis and logic that does not find any support in the references. **The Examiner, if he persists in this rejection, is requested to support his finding with adequate evidence.**

For these additional reasons, claims 11-17 are not shown, taught or made obvious by the references taken singly or in combination.

Accordingly, none of the claims in the application are shown, taught or made obvious by any of the references of record taken singly or in any combination.

In view of the foregoing comments, it is believed that all the claims presently in the application are in condition for allowance. Reexamination and reconsideration are requested. It